Claims 1, 3, 5, 7, 9, 11, 13 and 15 stand withdrawn from consideration as not reading on the elected invention.

It is again requested that these non-elected claims be rejoined with the claims of the elected invention should the elected claims become allowable. Note MPEP §821.04.

The elected claims are Claims 17-24. The only rejection of these claims still adhered to by the Examiner is under 35 U.S.C. §103(a) as being unpatentable over Canadian Patent No. 2,082,573 and European Patent No. 204,596, all other rejections having been withdrawn.

It is submitted that this also is not a viable rejection.

The invention relates to an oral or dermal medicinal composition containing a pharmaceutical active substance and a thermoplastic coating and binding agent prepared by a method of applying a thermoplastic coating and binding agent in a hot-melt liquid state to said oral or dermal medicinal composition, followed by cooling to solidify the thermoplastic coating and binding agent, wherein said thermoplastic coating and binding agent consists essentially of a non-homogenous mixture of, based on 100% by weight of A and B:

A) 5-95% of a thermoplastic acrylic plastic with a melting temperature above room temperature and below 200°C, a glass transition temperature below 120°C, and a melt viscosity pf 1,000 to 1,000,000 Pa-sec at the melting temperature; and

B) 95-5% of a flow improver, which, at room temperature, is not compatible with the thermoplastic acrylic plastic, has a melting temperature above room temperature but below 200°C, a weight average molecular weight under 20,000 d, and a melt viscosity below 100 Pa·sec at the melting temperature of the acrylic plastic.

Essential to the claimed invention is that components A and B form a non-homogenous mixture, e.g. components A and B are not compatible. This clearly is not the case in either the Canadian or European Patents, nor necessarily inherent therein.

Thus, the Canadian Patent in the paragraph bridging pages 2 and 3 discloses:

> ...a solid depot drug form product by melt extrusion at from 50 to 200°C and continuous shaping of a mixture of from 0.1 to 70% by weight, based on the finished depot form, of a pharmaceutical active ingredient with a polymer melt of the following composition:
>
> a) at least 6% by weight, based on the complete depot form, of at least one water-insoluble poly(meth)acrylate with a glass transition temperature Tg in the range of from -60 to 180°C,
>
> b) a water-soluble hydroxyalkylcellulose or hydroxy-alkylmethylcellulose with 2 or 3 carbons in the hydroxyalkyl, or an N-vinylpyrrolidone polymer with from 0 to 50% by weight of vinyl acetate or a mixture of the two
>
> in the ratio a):b) = 5:95 to 95:5, and
>
> c) 0-30% by weight, based on the finished depot form, of one or more conventional pharmaceutical auxiliaries,

In other words, it discloses a composition of a homogenous mixture of a) and b), optionally also containing component c). Such a composition clearly is distinctly different from the composition used in the preparation of the claimed medicinal composition consisting essentially of a non-homogenous mixture of A and B as defined by the claims. Even if optional component c) could, broadly, fall within the scope of claimed component B, nevertheless, the mixture in the Canadian Patent must be a homogenous, not a non-homogenous mixture, essential to the claimed invention.

Similarly, in the European patent two lipid excipients, one of which can dissolve or gel component A while the other acts as a lubricant, or, alternatively, a single lipid excipient having both of these functions is used in the extrusion of a medicinal material. Here again, the reference teaches away from the claimed invention in requiring that the composition be a homogenous mixture, i.e., containing a lipid excipient which can dissolve the gel component A. Such is contrary to the express requirement of the present claims wherein the mixture of A and B is specifically defined as consisting essentially of a non-homogenous mixture of A and B.

It is the Examiner's position that the compositions of the Canadian and European Patents would exhibit the claimed non-homogeneity once the mixture has solidified. The claims, however, specifically call for applying a non-homogenous mixture of the thermoplastic coating and binding agent in a hot-melt liquid state to an oral or dermal medicinal composition. As so disclosed at page 7, lines 5 to 8 of the specification:

> The incompatibility has the effect that in the solidified melt, components A and B are present as separate phases, and flow improver B is not present dissolved in polymer phase as a plasticizer.

It is thus essential that the initial mixture be non-homogenous, such non-homogeneity resulting in the above set forth effect. Using a homogenous mixture, as in the reference, palpably would not result in such an advantageous effect.

The defined incompatibility, i.e., non-homogenous mixture, has the effect that in the solidified melt, components A and B are present as separate phases, and flow improver B is not present dissolved in polymer phase A as a plasticizer. Such provides for an improved

flowing capacity of the melt, without a plasticizing effect which would lead to sticky surfaces. Such clearly is not obvious from the references.

As so requested by the Examiner, the claims have been amended to make it clear that the defined molecular weight is on a weight average basis, consistent with the disclosure.

It is submitted that the claims define a patentable invention. Their allowance, as well as of the method claims of the same scope to be rejoined with the product claims, thus is solicited.

Respectfully submitted,

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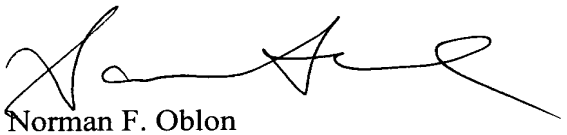

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